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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/726,627	12/04/2003	Stephan C. F. Gamard	D-21367	5738

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PRAXAIR, INC.  
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DANBURY, CT 06810-5113

EXAMINER
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LEWIS, KIANIRA CHARLE

ART UNIT	PAPER NUMBER
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3772

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/10/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

## Office Action Summary

Application No.

10/726,627

Applicant(s)

GAMARD ET AL.

Examiner

Kiandra C. Lewis

Art Unit

3772

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 11 May 2004 and 12 January 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-49 is/are pending in the application.
- 4a) Of the above claim(s) 1-37 and 44-49 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 38-43 is/are rejected.
- 7) ☒ Claim(s) 39 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12/04/03 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Claims 1-37 and 44-49 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 1/12/2007.

2. Applicant's election with traverse of claims 1-49 in the reply filed on 1/12/07 is acknowledged. The traversal is on the ground(s) that there is no serious burden on the examiner to search all three groups of invention. This is not found persuasive because the examiner has noted in the prior action that the claims of the inventions fall within different sub-classifications. Furthermore the inventions are distinct.

The requirement is still deemed proper and is therefore made FINAL.

### ***Specification***

3. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

### ***Claim Objections***

4. Claim 39 is objected to because of the following informalities: Claim 39 states "after step d" however there is no listing of method steps "a through d" in claim 38. Appropriate correction is required.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 38-41 rejected under 35 U.S.C. 102(b) as being anticipated by Samiotes US 6,125,84 in view of Jones, Jr. et al. US 5,724,986.

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As to claim 38, Samiotes discloses a method of introducing a drug from an inhaler to a spacer (col. 2, lines 53-65), said method comprising the steps of: providing a propellant gas at a predetermined pressure in an inhaler (col. 4, lines 47-49), injecting said propellant gas into a portion of the drug to aerosolize and fluidize said drug in the inhaler, thereby producing a drug cloud (col. 7, lines 5-9); and injecting said drug cloud into said spacer (col. 6, lines 16-18).

As to claim 39, there may be a laminar flow of the drug cloud (controlled via the breath activated mechanism).

9. As to claim 40, Samiotes discloses Helium as a possible propellant gas (col. 6, lines 20-28).

As to claim 41, Samiotes discloses that the pressure of the propellant is reduced from 1500-3000psi to about 25 psi. It would have been obvious to one having ordinary skill in the art that the range of the propellant being between 200 psi and 50 psi is in the range of about 25 psi, in the broadest sense. Furthermore the applicant has not stated any criticality to the particular range of pressure by stating that it serves a particular purpose, solved a stated problem, or provides an advantage. Thus it is evident that the invention of Samiotes. would perform equally as well with a pressure of less than 1500-3000 psi, particularly about 25 psi.

10. Claims 42 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Samiotes '844 and Jones, Jr. et al. '986 and in further view of Seppala US 6,948,495.

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As to claim 42, Samiotes and Jones, Jr. et al. disclose the limitations of the base claim but does not expressly state that the device has a drum between propellant gas and said spacer. Seppala teaches the use of a drum (col. 3, lines 9-15) in an inhalation device in which there are one or more tubes (recesses). Seppala further teaches rotating the drum so that each tube (recesses) may obtain a dose of medication by being rotated. It would have been obvious to one having ordinary skill in the art to include the drum as taught by Seppala in the invention of Samiotes for the purpose of regulating dosing.

As to claim 43, the above combination teaches there may be a laminar flow of the drug cloud (controlled via the breath activated mechanism).

### ***Double Patenting***

11. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

12. Claims 38-43 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 38-43 of copending Application No. 10/845411. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

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13. As to claims 38-43, the claims of the instant application are identical to the claims of the copending application.

**Conclusion**

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. 5,724,986.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kiandra C. Lewis whose telephone number is 571-272-7517. The examiner can normally be reached on Mon-Thurs 9AM-6PM and alternating Fridays 9AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on 571-272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KCL

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4/2/07